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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,452	12/30/2003	Michael J. Bonnette	POSSIS	2399

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EXAMINER
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JOHNSON, JERROLD D

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/748,452	<b>Applicant(s)</b> BONNETTE ET AL.	
	<b>Examiner</b> Jerrold Johnson	<b>Art Unit</b> 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of the restriction requirement in the reply filed on 05/05/05 is acknowledged. The ground(s) on which traversal is made is not fully understood by the Examiner, and, accordingly, is not found persuasive. The Applicant asserts that the Examiner has misincorporated logic in the analysis leading to the restriction, by misidentifying the inventions disclosed within the Application. The Applicant further asserts that the product, as set forth in claims 9-21, should be viewed as a "precursor" for the method claims 1-8.

Firstly, the Examiner is unaware how the status of invention set forth claims 9-21 as a "precursor" either negates or precludes the invention being set forth in those claims as a product, as set forth in the restriction requirement. Additionally, the Examiner again asserts that the product of claim 9 can be made without evacuating (a process requiring a vacuum) air as is set forth in the method claim 1, specifically, the product can be made in an environment where air is not removed via vacuum, but through a purging process. Therefore the inventions are distinct from each other, and the restriction is proper.

The requirement is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 9, 12, 13 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by George US 5,014,494.

Re claim 9, George provides a plastic/foil laminate sealable container for plastic medical articles that need to undergo gamma radiation in the absence of oxygen, lest they also be subject to deterioration through yellowing. George discloses the isolation of the medical article from ambient atmosphere while the article is in the container. And, George discloses several polymer plastics by example which are known to yellow post gamma radiation. For those plastics that yellow in the presence of oxygen post gamma radiation, yellowing will occur in the package of George should the package be opened within the time window that the plastic is sensitive to oxygen. Accordingly, George inherently discloses a product which provides a visual oxygen sensing indicator (the medical article).

Re claim 12, George further inherently discloses a storage arrangement wherein wherein the visual change of the oxygen-sensitive material indicates a failure of the sealable container. Specifically, if the container has failed and oxygen is let into the container, yellowing will occur in those plastics disclosed by George which yellow in the presence of oxygen post gamma radiation.

Re claim 13, George discloses various polymer plastics by way of example in col. 2, lines 28 and 29.

Re claim 21, George discloses medical devices.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 11,15-17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over George US 5,014,494 in view of Nicolais US 6,161,695, Ahlqvist et al US 5,881,534 and Examiner Official Notice.

George does not explicitly set forth a "piece" of oxygen sensitive material.

The Examiner submits that "a piece" can be construed as a single medical device, which is what is disclosed by Nicolais.

George also does not explicitly set forth the plastic/foil laminate as set forth in claims 16 and 17, but does disclose in col 2, line 47, impermeable containers using foil which are necessary for the sterilization in the absence of oxygen.

Nicolais, discloses a gas-impermeable foil pouch having a polymer/foil construction (the well known construction of impermeable pouches) and an outer cardboard protective packaging. Nicolais does not disclose the exact foil pouch laminate as set forth in claim 17. However, it is submitted that this laminate is known in the prior art, as there are literally hundreds of such laminates used in the medical industry. And, Applicant devoted a single sentence to this laminate, which suggests that this laminate is merely an off the shelf laminate known in the art.

Ahlqvist discloses in col. 8 lines 1-12 laminates having PET layers, and the known irradiation dose of 35 kGy, which is a common radiation dose used in sterilization of medical devices.

Accordingly, it would have been obvious to modify the container of George with the teachings of using a single medical device in the sealed container during sterilization, so that if oxygen is present and the device yellows, the situation will be easily visually identified.

Additionally it would have been further obvious to have used a gas-impermeable foil pouch within a cardboard packaging, as disclosed by Nicolais, as such foil pouches are known for their impermeability to air, a necessity set forth by George, and to protect the pouch with a cardboard packaging to protect the foil pouch from puncture.

With respect to claim 15, it would be obvious to use a range for the amount of gamma radiation from 25 kGy to 45 kGys as disclosed by Ahlqvist, as that is the range commonly used to sterilize medical devices, and is within the capabilities of the equipment already used for this purpose.

With respect to the specific laminate set forth in claim 17, the Examiner submits that such a laminate is well known in the art. For economic reasons, it would be obvious to use a known polymer foil laminate in the construction of the pouch.

With respect to the rate at which material undergoes change, as is set forth in claims 19 and 20, it is submitted that there are polymers that are known to undergo yellowing immediately following radiation if oxygen is present. Accordingly, these claims are not patentable.

3. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over George US 5,014,494 in view of Sleenckx US 6,166,116.

George discloses by example several plastics which are known to yellow post gamma radiation, but does not identify polycarbonate specifically.

The prior art is replete with different polycarbonate compositions each of which have been formulated to minimize the yellowing which occurs as a result of the common practice of gamma sterilization. Many of these formulations have high sensitivity to the presence of oxygen post gamma sterilization, and therefor must be sterilized in an oxygen free environment. Funakoshi et al. US 6,485,657 provides extrinsic evidence of this fact in col. 2, paragraph 1. DeRudder et al. US 5,196,245, in col. 8 lines 46-60 further evidences this fact.

Sleenckx, in col. 9, lines 14-32, discloses such a polycarbonate formulation. Note that there is a typo in this recitation, specifically, "absence" in line 16, clearly should be "presence". Col. 10 lines 29+ provides an example of the testing performed in the absence of oxygen.

It would have been obvious to one of ordinary skill in the art to have used the sealable container of George with the polycarbonate plastic disclosed by Sleenckx, so as to properly shield the polycarbonate of Sleenckx from oxygen during the sterilization process to minimize yellowing.

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3. Claim 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over George US 5,014,494 in view of Archey US 5,399,658 and Lewis US 2004/0050740.

George does not disclose planar chips or symbols used in the oxygen sensitive material.

Archey et al., in col. 7 lines 30+ discloses ASTM guidelines for testing polycarbonate yellowing using planar chips of polycarbonate subject to gamma radiation.

Lewis, discloses a polycarbonate chip (para. 0019) used as an oxygen sensor. The chip includes a symbol, and the chip is separate from, but used with other elements such as pharmaceuticals.<sup>3</sup>

Accordingly, it would have been obvious to have used planar chips, as taught by Lewis, as oxygen sensors in the package of George to detect oxygen in the container, as thin planar chips would likely undergo yellowing quicker than the thicker materials used in medical devices. Additionally, it would be further obvious to include a symbol, as is taught by Lewis so as to make the identification of a visual change easier.

### ***Conclusion***

Applicant appears to be claiming as their invention properties of polycarbonate that are so well known as to be set forth in ASTM testing procedures.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ



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